

Abstract

Binding assay employing labelled reagent

A binding assay process for an analyte, in which process a capture binding agent having binding sites specific for the analyte and a developing binding material capable of binding with the bound analyte or with the binding sites on the capture binding agent occupied by the bound analyte or with the binding sites remaining unoccupied on the capture binding agent are used, employs the capture binding agent in an amount such that only an insignificant fraction of the analyte in the sample becomes bound to the capture binding agent, the capture binding agent preferably being present at high surface density on microspots. A label is used in the assay in relation to the developing binding material, the label being provided by microspheres having a size of less than 5  $\mu\text{m}$  and carrying a marker, preferably fluorescent dye molecules contained within the microspheres. For determination of the concentration of the analyte in the sample the strength of the signal is representative of the fractional occupancy of the binding sites on the capture binding agent by the analyte and a comparison is made with a dose-response curve computed from standard samples. For detection of an analyte comprising a single-stranded DNA sequence the presence of the analyte is detected by the existence of a signal. A kit for the process comprises a solid support having the capture binding agent immobilised on it, a developing reagent comprising the developing binding material attached to the microspheres and, where concentrations are to be measured, standards having known amounts or concentrations of the analyte to be determined.